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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,682	07/30/2007	Alberto Hayek	UCSD-104-US	8815

59241 7590 10/07/2009  
LATIMER, MAYBERRY & MATTHEWS IP LAW, LLP  
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HERNDON, VA 20171

EXAMINER
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ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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10/07/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

JEN.CORTESE@LATIMERIP.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,682	<b>Applicant(s)</b> HAYEK ET AL.	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not

5 so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1–21(in part) and 61(in part), drawn to a method comprising exposing a stem  
10 cell to a TGF $\beta$  family member.

Group II, claim(s) 1–21(in part) and 61(in part), drawn to a method comprising exposing a stem  
cell to an FGF family member.

15 Group III, claim(s) 1–21(in part) and 61(in part), drawn to a method comprising exposing a stem cell to NIC.

Group IV, claim(s) 23–39(in part), 55(in part) and 62(in part), drawn to a composition  
comprising a TGF $\beta$  family member.

20 Group V, claim(s) 23–39(in part), 55(in part) and 62(in part), drawn to a composition comprising an FGF family member.

Group VI, claim(s) 23–39(in part), 55(in part) and 62(in part), drawn to a composition  
25 comprising NIC.

Group VII, claim(s) 23–39(in part), 40–46 (in part), 55(in part) and 62(in part), drawn to a  
composition comprising a TGF $\beta$  family member and an FGF family member.

30 Group VIII, claim(s) 23–39(in part), 40–46 (in part), 55(in part) and 62(in part), drawn to a composition comprising a TGF $\beta$  family member and NIC.

Group IX, claim(s) 23–39(in part), 40–46 (in part), 55(in part) and 62(in part), drawn to a  
composition comprising an FGF family member and NIC.

35 Group X, claim(s) 23–39(in part), 40–46 (in part), 55(in part) and 62(in part), drawn to a composition comprising a TGF $\beta$  family member, an FGF family member and NIC.

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Group XI, claim(s) 55(in part), 47–54(in part), 64, 65 and 66(in part), drawn to a composition comprising a stem cell grown or maintained in a medium comprising a TGF $\beta$  family member.

5 Group XII, claim(s) 55(in part), 47–54(in part), 64, 65 and 66(in part), drawn to a composition comprising a stem cell grown or maintained in a medium comprising an FGF family member.

Group XIII, claim(s) 55(in part), 47–54(in part), 64, 65 and 66(in part), drawn to a composition comprising a stem cell grown or maintained in a medium comprising NIC.

10 Group XIV, claim(s) 63(in part) and 66(in part), drawn to a composition comprising a differentiated cell derived from a stem cell grown or maintained in a medium comprising a TGF $\beta$  family member.

15 Group XV, claim(s) 63(in part) and 66(in part), drawn to a composition comprising a differentiated cell derived from a stem cell grown or maintained in a medium comprising an FGF family member.

20 Group XVI, claim(s) 63(in part) and 66(in part), drawn to a composition comprising a differentiated cell derived from a stem cell grown or maintained in a medium comprising NIC.

25 The inventions listed as Groups I–XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: According to the European search report, the growth or maintenance of stem cells with a TGF $\beta$  family member or an FGF family member cannot be considered novel or to involve an inventive step. The growth or maintenance of stem cells with nicotinamide is also well-known in the art. See, for example, Peled (U. S. Publication No. 20050008624). Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. It follows that stem cells are well known in the art. The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Therefore, Groups I–XVI cannot be considered novel or to involve an inventive step.

35 Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

40 The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/  
PRIMARY EXAMINER, ART UNIT 1647

DSR  
SEPTEMBER 30, 2009